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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/660,051	09/11/2003	Antonio Ruiz		7800

7590 03/22/2006

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EXAMINER	
AUDET, MAURY A	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 03/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/660,051	RUIZ ET AL.	
	Examiner	Art Unit	
	Maury Audet	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-13* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept.

In accordance with 37 CFR 1.142 applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-12, drawn to a method of treating a Gram-positive bacterial infection comprising administering a F_1F_0-ATP synthase inhibitor selected from the efrapeptin Markush group consisting of SEQ ID NOS: 1, 2, 3, 4, and 5, classified in class 514, subclass 2+.

II. Claims 1-12, drawn to a method of treating a Gram-positive bacterial infection comprising administering a F_1F_0-ATP synthase inhibitor selected from the Markush group consisting of IF_1, aurovertins, citreoviridin, citreoviridin acetate, quercetin, oligomycins, peliomycin, N,N'-Diclycohexylcarbodiimide, venturidicidins, trimethyl tin chloride, DBCT, ossamycin, and leucinostatin non-sterically hindered and sterically hindered thioester or selenoester generators, classified in class 514, subclass 2+.

III. Claim 13, drawn to an assay for determining whether a molecule inhibits the growth of Gram-positive bacteria by inhibiting the enzymatic activity of F_1F_0-ATP synthase, the method comprising a screening assay in which the possible inhibition of F_1F_0-ATP synthase by the molecule is determined by adding the substance to a system comprising immobilized F_1F_0-ATP synthase and soluble ATP, enzymatic activity detected by coupling the production of ADP

to the oxidation of NADH via pyruvate kinase and lactate hydrogenase reactions, classified in class 514, subclass 2+.

The inventions are distinct, each from the other because of the following reasons:

The methods of Groups I-III are directed to different inventions, which are not connected in design, operation, and/or effect. These methods are independent since they are not disclosed as capable of use together, they have different modes of operation, they have different functions, and/or they have different effects. One would not have to practice the various methods at the same time to practice just one method alone.

The several inventions above are independent and distinct, each from the other. They have acquired a separate status in the art as a separate subject for inventive effect and require independent searches. The search for each of the above inventions is not co-extensive particularly with regard to the literature search. Further, a reference, which would anticipate the invention of one group, would not necessarily anticipate or even make obvious another group. Finally, the consideration for patentability is different in each case. Thus, it would be an undue burden to examine all of the above inventions in one application. Restriction for examination purposes is therefore proper.

Because these inventions are distinct for the reasons given above and the search required for each group is not necessarily required for the other groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

During a telephone conversation with Adonia Papathanasiu, Pro Se Applicant, on 03/15/2006, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claim 13 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Papathanasiu (US 6,528,489) or Abrahams et al. (Proc. Natl Acad Sci, 1996, 93(18): 9420-4) in view of Barry et al. (US 5,610,198).

Papathanasiu expressly teaches the efrapeptin Markush group consisting of SEQ ID NOS: 1, 2, 3, 4, and 5 (Fig. 3), and that these compounds are use for treating diseases (abstract) and known antibiotics (col. 1, line 13; col. 2, lines 51-52). However, even though antibiotics are known treat bacterial infections, Papathanasiu does not expressly list species of bacterial infections such as Gram-positive bacterial infections (e.g. mycobacterial) or the use of these antibiotics for Gram-positive bacterial infections or the use of these efrapeptin antibiotics with another antibiotic, to synergistically reduce or inhibit mycobacterial infections.

Abrahams et al. also expressly teaches the efrapeptin Markush group consisting of SEQ ID NOS: 1, 2, 3, 4, and 5 (Fig. 1), and that these compounds are known antibiotics capable of working generally among bacteria at the cellular level of ATP synthesis and hydrolysis by binding to the F_1 catalytic domain of F_1F_0-ATP synthase (abstract, 1st para.). However, even though antibiotics are known treat bacterial infections, Abrahams et al. does not expressly list species of bacterial infections such as Gram-positive bacterial infections (e.g. mycobacterial) or

the use of these antibiotics for Gram-positive bacterial infections or the use of these efrapeptin antibiotics with another antibiotic, to synergistically reduce or inhibit mycobacterial infections.

Barry et al. expressly teach that the genus of bacterial infections, capable of being treated with antibiotics, includes the species of Gram-positive bacterial infections, such as mycobacterial infections (col. 1) and that mycobacterial infections such as mycobacterium tuberculosis, are routinely treated with more than one antibiotic, as a combination therapy (col. 3, lines 15-25), and that other antibiotics are contemplated for use in this combination as well (col. 11, lines 55-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to treat the bacterial species group of Gram-positive bacterial infections, such as mycobacterial infections, using the antibiotic efrapeptins of SEQ ID NOS: 1-5, alone or in combination, in Papathanasiu or Abrahams et al., because Barry et al. advantageously teach that the genus of bacterial infections, capable of being treated by antibiotics, includes the species Gram-positive bacterial infections, which may be treated alone or in combination; in light of the non-limiting teachings of Papathanasiu's teachings of these efrapeptins capability to treat the genus of bacterial infections and Abrahams et al.'s teaching of the same as well as the general mechanism by which these efrapeptin's are able to attach any bacterial organism's central ATP processing.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 03/16/2006

MAURY AUDET
PATENT EXAMINER
ART UNIT 1654